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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,226

02/22/2005

Junichi Ninomiya

SIG-008

7185

32628

7590

04/09/2008

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ALEXANDRIA, VA 22314-2848

EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

04/09/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/525,226	<b>Applicant(s)</b> NINOMIYA ET AL.	
	<b>Examiner</b> LAURA A. BOUCHELLE	<b>Art Unit</b> 3763	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 December 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Response to Amendment***

***Claim Rejections - 35 USC § 102***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 2, 4, 5, 6, 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Chevalier (FR 2619301). Chevalier discloses a device for extracting segments of veins comprising a first wire 3, a second wire 10, an intermediate wire 11, connecting means 9 provided on the end of each wire, an insert head 5, the intermediate wire connected to the first and second wires by the connecting means, and a vein ligating portion formed by the connecting portions. See Fig. 1.

***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 3, 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chevalier in view of Goldberg et al (US 5601580).
5. Claim 3 differs from Chevalier in calling for the connecting means to be a screw. Goldberg reaches a venous valve cutter having a similar structure to that of Chevalier but wherein the connecting means is a screw that allows for easy and secure connection of the removable portions. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Chevalier to include screws as taught by Goldberg because screws are known connecting means in the art and provide secure and easily removable connections.

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6. Claim 7 differs from Chevalier in calling for the head to be an olive shape. Goldberg teaches a vein remover having an olive shaped head that allows the device to be easily inserted into the vein but not removed. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Chevalier to include an olive shaped head as taught by Goldberg so that the device can be easily inserted into the vein but then catch on the inner walls of the vein when it is removed.

7. Claims 9, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chevalier in view of Nobles (US 5026383). Claim 9 calls for the wire to have an outer diameter of 1.5-3.0 mm. Chevalier is silent as to the diameter of the wire, but is sized to be inserted into a vein. Nobles teaches an apparatus for cutting veins comprising a wire having an outer diameter of 2.0 or 2.5 mm to allow the catheter to be inserted into the desired portion of a vein (Col. 4, lines 33-36). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Chevalier to have an outside diameter of 2.0-2.5 mm as taught by Nobles so that the device can be inserted into a vein.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chevalier in view of Nobles as applied to claim 9 above, and further in view of Iwatschenko (US 4306563). Claim 10 differs from the teachings above in calling for the surface of the device to be coated. Iwatschenko teaches a catheter for insertion into the body having a coating of silicone resin to increase the compatibility within the body and to prevent toxic reactions (Col. 1, lines 48-51). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Chevalier in view of Nobles to have a silicone resin coating as taught by Iwatschenko to increase biocompatibility and prevent toxic reactions.

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9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chevalier in view of Nobles in view of Iwatschenko as applied to claim 10 above, and further in view of Weiss (US 4880412). Claim 11 differs from the teachings above in calling for the device to have depth marks. Weiss teaches a device for inserting catheter tubes having a catheter with marks at regular intervals to show the depth of penetration of the catheter into the vein (Col. 7, lines 43-47). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device above to have depth markers as taught by Weiss so that the user can determine how far the device has been inserted into the vein.

10. Claims 13-18, 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ouriel et al (US 4952215) in view of Chevalier. Ouriel teaches a valvulotome having a first catheter portion and a second catheter portion with a ligating portion 40 therebetween, the first catheter portion is attached to an olive shaped head 50, and further having a fluid supply comprising a fluid supply tube 60 and a fluid coupling 75 to allow fluid to be delivered to the vein.

11. Claim 13 differs from Ouriel in calling for the catheter to include connecting portions to connect the first and second portions of the catheter. Chevalier teaches a vein ligating device having a first and second portions and an intermediate portion therebetween, the first and second portion being connected by connecting means that allows the user to assemble the device with the portions of the proper size and length for the intended use. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Ouriel to include connecting means as taught by Chevalier to allow user to assemble the device with the portions of the proper size and length for the intended use.

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12. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ouriel in view of Chevalier as applied to claim 14 above, and further in view of Sekino et al (US 4977902). Claim 19 differs from Ouriel in view of Chevalier in calling for a supersonic wave irradiating means. Sekino teaches a catheter having a supersonic irradiating means to treat a diseases portion of the body. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Ouriel in view of Chevalier to have an irradiating means as taught by Sekino to treat the diseased portion of the body.

13. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ouriel in view of Chevalier as applied to claim 14 above, and further in view of Sinofsky (US 5196004). Claim 20 differs from the teachings above in calling for a laser beam irradiating means. Sinofsky teaches a catheter having a laser that delivers irradiating energy to a biological tissue for removal or repair. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Ouriel in view of Chevalier to have a laser beam irradiating means as taught by Sinofsky to remove or repair tissue.

#### ***Response to Arguments***

14. Applicant's arguments with respect to claims 2, 13 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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